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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,326	08/30/2001	Martin Gleave	UBC.P-020-2	2324
21121	7590	07/28/2005	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			VIVLEMORE, TRACY ANN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,326

Applicant(s)

GLEAVE ET AL.

Examiner

Tracy Vivlemore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1, 12-15, 19 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 19 and 23 is/are rejected.
- 7) ☒ Claim(s) 12-15 and 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The finality of the last Office Action has been withdrawn and prosecution reopened in view of the after-final amendment submitted June 26, 2005.

Claim Rejections - 35 USC § 102

The incorporation of the subject matter of canceled claim 3 into claim 1 has obviated the rejection of record over Sensibar et al.

Claim Objections

1. Claims 14 and 15 are objected to because of the following informalities: each of these claims depends from a claim directed to a composition containing two antisense oligonucleotides. It appears that these claims are meant to limit the antisense oligonucleotide targeted to TRPM-2, thus for the sake of clarity, it is suggested that these claims be amended to refer to the "first" antisense oligonucleotide. Appropriate correction is required.
2. Claim 24 is objected to because of the following informalities: this claim contains non-grammatical English. The claim limits the composition of claim 1 by stating there is "an additional antisense oligonucleotide binds specifically". It is suggested that the word "that" be placed before the word "binds". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the tumor cells" in line 2. There is insufficient antecedent basis for this limitation in the claim. Removal of the word "the" would be remedial.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).



Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,900,187. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claim of the patent anticipates the generic claim to the same sequence in the instant application. Claim 19 is directed to an oligonucleotide consisting of SEQ ID NO: 4. The claim of the patent is directed to a compound consisting of SEQ ID NO: 4 that recites specific nucleobase, backbone or sugar modifications. Although these specific modifications are not contemplated in the instant application, the sequence in both of the claims is identical, thus the species claimed in the patent anticipates and is an obvious variation of the generic claim of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (European Journal of Biochemistry 1994, vol. 221, pages 917-925) and EMBL accession number M63376 in view of Baracchini et al. (US 5,801,154).
2. Wong et al. teach the molecular structure of human TRPM-2. Wong et al. further teach that this gene is associated with numerous disorders, including Alzheimer's, epilepsy and retinitis pigmentosa. Wong et al. submitted their sequence to a nucleotide database under accession number M63376. The sequence shown in this accession number comprises a sequence (shown at nucleotides 5538-5558) that is the complement of SEQ ID NO: 4. Wong et al. do not teach antisense inhibition of TRPM-2.
3. Baracchini et al. teach at column 4, lines 23-36 that antisense oligonucleotides can be formulated into compositions for pharmaceutical use as therapeutics and that these compositions can include a lipid carrier.
4. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cDNA transcript of the TRPM-2 gene taught by Wong et

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al. as a guide to make an antisense oligonucleotide fully complementary to the sequence taught by Wong et al. that inhibit expression of TRPM-2 in any type of cell expressing the gene and would contain the sequence identified as SEQ ID NO: 4. Wong et al. provide a motivation to do so, teaching that TRPM-2 is implicated in several diseases. It is well known in the art to make antisense oligonucleotides to inhibit expression of genes implicated in disease and it is further well-known in the art that antisense oligonucleotides can be a sequence fully complementary to a cDNA. It would have further been obvious to formulate that antisense oligonucleotide as a pharmaceutical composition suitable for administration to humans in order to use the composition as a therapeutic in a mammalian subject. One of ordinary skill in the art would have had a reasonable expectation of success in making an antisense oligonucleotide complementary to the sequence taught by Wong et al. and formulating it as a pharmaceutical suitable for human administration because methods of making oligonucleotides complementary to the full length of a sequence are well-known in the art and pharmaceutically acceptable carriers for administration of therapeutics to humans is similarly well-known in the art.

Allowable Subject Matter

SEQ ID NOS: 4 and 13 are free of the prior art searched.

Claims 12-15 and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811.

On July 15, 2005, the Central FAX Number will change to 571-273-8300.
This new number is already operational and faxes sent to the old number (703-872-9306) will be routed to the new number until September 15, 2005.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It


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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

TV
July 18, 2005

Tracy Vivlemore
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